

§ 807.26

21 CFR Ch. I (4–1–14 Edition)

any listing information requested by FDA under §807.26(e), in paper form using the procedures set forth in §807.34. The information required for each device listed includes:

(1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed.

(2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976.

(3) The proprietary or brand name(s) under which each device is marketed.

(4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, granted de novo classification petition, or approved humanitarian device exemption for each device listed that is subject to sections 505, 510(k), 513(f)(2), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, which includes devices that are not exempt from premarket notification and approval.

(5) Each activity or process that is conducted on or done to the device at each establishment, such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only.

[77 FR 45942, Aug. 2, 2012]

§ 807.26 Additional listing information.

(a) Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

(1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;

(2) For each restricted device, a copy of all labeling and advertisements for the device;

(3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels,

package inserts, and a representative sampling of any other labeling.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made any-time after initial listing.

(c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discontinued device by an owner or operator.

(d) Location of the file:

(1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.

(2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.

(3) A copy of the certification and disclosure statements as required by part 54 of this chapter shall be retained and physically located at the establishment maintaining the historical file.

(e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon specific request, the following information:

(1) For a device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device.

(2) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where

feasible, be accompanied by an explanation of the basis for such request.

(3) For a device that is neither a restricted device, nor subject to section 514 of 515 of the act, the label and package insert for the device and a representative sampling of any other labeling for the device.

(4) For a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(5) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device.

(6) For a particular device, a statement of the basis for determining that the product is a device rather than a drug.

(7) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

(f) Labeling, advertisements, and other information to be submitted upon request in accordance with paragraph (e) of this section may be submitted by postal mail or electronically by email, but will not be submitted using the FDA electronic device registration and listing system. Electronic submissions of such information must comply with part 11 of this chapter, except for the requirements in §11.10 (a), (c) through (h), and (k), and the corresponding requirements in §11.30 of this chapter. The information provided in electronic format must be in a form that we can process, review, and archive.

[43 FR 37999, Aug. 25, 1978, as amended at 51 FR 33033, Sept. 18, 1986; 63 FR 5253, Feb. 2, 1998. Redesignated and amended at 77 FR 45943, Aug. 2, 2012]

§ 807.28 Updating device listing information.

(a) Updating of device listing information is required if an additional establishment begins to engage in any of the activities described in §807.3(d) with respect to a listed device, such as manufacturing, developing specifications, repackaging, relabeling, or otherwise processing the device. Updating of the listing is also required if an es-

tablishment begins performing another activity on or to the device, or ceases to perform an activity on or to the device that had previously been identified on the device listing.

(b) An owner or operator shall create a new device listing using the FDA electronic device registration and listing system:

(1) If introducing into commercial distribution an exempt device identified with a product code that is not currently listed by the owner or operator; or

(2) If introducing into commercial distribution a non-exempt device with an FDA premarket submission number that is not currently listed by the owner or operator.

(c) All device listings for foreign establishments must be submitted before the device may be imported or offered for import into the United States.

(d) An owner or operator who discontinues commercial distribution of a device shall discontinue the device listing using the FDA electronic device registration and listing system. A device listing is considered discontinued if:

(1) All devices under an exempt product code have been discontinued or

(2) All devices associated with an FDA premarket submission number have been discontinued.

(e) If commercial distribution of a discontinued device is resumed, the owner or operator must reactivate the previously-discontinued listing using the electronic device registration and listing system. Any changes to the listing information for the product that is the subject of the listing such as a new establishment, new activity, or new proprietary name must be made using the electronic device registration and listing system at the time the listing is reactivated.

(f) FDA will assign one listing number for all devices exempt from premarket notification requirements under a single product code. For products not exempt from premarket notification requirements, a single listing number will be assigned by FDA for each FDA premarket submission number.

[77 FR 45943, Aug. 2, 2012]